Statement of Philip S. Johnson,
Chief Patent Counsel,
Johnson & Johnson

Before the

Subcommittee on Courts, the Internet, and
Intellectual Property of the
Committee on the Judiciary
House of Representatives

On

"An Amendment in the Nature of a Substitute to H.R. 2795, the Patent Act of 2005"

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10 a.m.

Executive Summary of Testimony of Philip S. Johnson

PhRMA and Johnson & Johnson thank the Subcommittee for the opportunity to testify on the "Amendment in the Nature of a Substitute to H.R. 2795, the Patent Act of 2005" (the "Substitute") as well as the so-called "Coalition Text" which has been submitted to the Subcommittee as a proposed amendment to the Substitute. Mr. Johnson, Johnson & Johnson's Chief Patent Counsel, appears at today's hearing as the designee of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), as well as on behalf of Johnson & Johnson. PhRMA and Johnson & Johnson appreciate the opportunity to present our views on the Substitute and Coalition Text and thank the Subcommittee for maintaining open and transparent discussions concerning an issue as important as patent law reform.

PhRMA member companies, including Johnson & Johnson, are substantial patent owners and users of all aspects of the patent system. PhRMA supports good quality patents and a patent system that provides fair and effective incentives for innovation. Legislative changes that diminish the value of patents will have an immediate detrimental impact on decision makers considering investing in R&D-based ventures, and will negatively affect needed long-term innovation.

PhRMA opposed the original text of H.R. 2795 due primarily to the inclusion in that text of various provisions that were seen as diminishing the value of patents and/or as being detrimental to the patent system. Principal among these were provisions relating to injunctions and the so-called "second window" for bringing post-grant patent oppositions.

While PhRMA recognizes that the Substitute represents substantial progress from the original text of H.R. 2795, especially in view of the removal of many of the negatively-viewed provisions in the original text of the bill many PhRMA companies have expressed substantial concerns with several of the provisions of the Substitute. The concerns were initially with its newly introduced venue provision, but more recently have included the suggested interpretation of the term "inventive contribution" in the damages apportionment provision that would lead to trivializing patent damages.

PhRMA has no official position on the Coalition Text circulated by the Subcommittee, but recognizes that the Coalition Text is supported by some 30 companies from various industries, including several of PhRMA's member companies. The Coalition Text is seen by Johnson & Johnson and many other companies as representing a fair and achievable approach to patent law reform. It differs in several material respects from the Substitute in that it more fully preserves the CREATE Act, provides a fair and workable approach to venue in patent cases, and clarifies the codification of *Georgia Pacific* factor #13 while avoiding any unintended derogation of patent damages.

Testimony of Philip S. Johnson

Mr. Chairman and distinguished members of the Subcommittee:

Thank you for providing me this opportunity to testify on the "Amendment in the Nature of a Substitute to H.R. 2795, the Patent Act of 2005" (the "Substitute") as well as the so-called "Coalition Text" which has been submitted to the Subcommittee as a proposed amendment to the Substitute. I appear today as the designee of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), as well as on behalf of Johnson & Johnson. PhRMA and Johnson & Johnson appreciate the opportunity to present our views on the Substitute and Coalition Text and thank the Subcommittee for maintaining open and transparent discussions concerning an issue as important as patent law reform.

Introduction

By way of introduction, I am a registered patent attorney with 32 years of experience in all aspects of patent law. In addition to drafting and prosecuting patent applications, I have tried patent cases to both judges and juries, and have advised a wide variety of clients in many industries ranging from semi-conductor fabrication to biotechnology. Over the course of my career, I have been pleased to have represented individual inventors, universities, start-ups, and companies of all sizes. In January of 2000, I left private practice to join Johnson & Johnson as its Chief Patent Counsel, which is the position I hold today.

PhRMA is an industry association that represents the country's leading pharmaceutical research and biotechnology companies devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA members invested an estimated $38.8 billion in 2004 in discovering and developing new medicines. PhRMA companies lead the way in the search for new cures.

Johnson & Johnson is a family of more than 200 companies, and is the largest broad-based manufacturer of health and personal care products in the world. Collectively, Johnson & Johnson companies represent this country's largest medical device business, its second largest biotechnology business, its fourth largest pharmaceutical business, and very substantial consumer, nutritional, and personal care businesses. Johnson & Johnson companies employ over 55,000 Americans, 7,000 in California alone.

Johnson & Johnson is a member of PhRMA, as well as other industry organizations such as BIO (the biotechnology industry association) and Advamed (the medical device industry association). I currently serve as co-chair of PhRMA's IP/Patents Focus Group, as vice-president of the Association of Corporate Patent Counsel, as Chair of the Board of Directors of the American Intellectual Property Association Education Foundation, and on the amicus committees of the Intellectual Property Owners Association ("IPO") and the American Intellectual Property Law Association ("AIPLA").

Johnson & Johnson's companies are research-based businesses that rely heavily on the U.S. patent system and its counterpart systems around the world. In the past two years alone, Johnson & Johnson's businesses have invested close to $10 billion in R&D. The inventions resulting from Johnson & Johnson's research are reflected in the filing of over 2,000 U.S. patent applications during this period. Johnson & Johnson companies have been awarded over 900 patents in the last two years, and now hold nearly 42,000 patents, of which nearly 7,000 are U.S. patents.

As the manufacturer and marketer of thousands of products, the freedom to make and sell products in view of the patents of others is always a concern of Johnson & Johnson businesses. They therefore routinely review hundreds of patents during their product development processes, make appropriate design changes to avoid the patents of others and/or obtain appropriate licenses or legal opinions prior to launching their products. Nonetheless, Johnson & Johnson companies do from time to time become involved in patent litigation, finding themselves to be defendants about as often as they are plaintiffs. Most of these litigations involve competitors or would-be competitors, although some involve non-manufacturing patentees.

Policy Considerations Driving Patent Reform

Patent law reform means different things to different people. For example, some proponents focus on enhancing the quality of patents issued by the U.S. Patent and Trademark Office. Other proponents have focused on litigation reform. The recent reports issued by the Federal Trade Commission ("FTC") and the National Academies' Board on Science, Technology, and Economic Policy ("NAS") surveyed the landscape and made many thoughtful recommendations.

While patents are a principal driver of innovation in many technologically-based industries, they are perhaps most important in the pharmaceutical and biotechnology industries. In industries in which it takes 8 to 10 years or more, and hundreds of millions of dollars, to develop, test and obtain approvals for a single product, patents are critical. No pharmaceutical company wants to commit this magnitude of investment to the development of a drug product only to later find that the patent was invalid or unenforceable due to an error in its examination, or because of previously undiscovered prior art.

The perceived predictability and reliability of patent protection weighs heavily on business planners in deciding whether to go forward with the investments needed to develop potentially promising new drugs. As a matter of sound public policy, we urge the Subcommittee to support changes that encourage investment decisions to be made based upon the potential importance of the new technology rather than on whether the patent examination process is or has been flawlessly conducted. As Chief Judge Sue Robinson of Delaware recently noted in her speech to the Association of Corporate Patent Counsel, patent litigation has become more a matter of semantics than of science. In Johnson & Johnson's view, this trend is taking patent law in the wrong direction. Instead, we believe that the rewards promised by the patent system should closely track

the value of the invention's contribution to society, not the skills of those who happen to have been involved in drafting, prosecuting or examining the patent application. Just as plainly invalid patents (i.e., those purporting to cover that which contribute nothing to society) are a drag on the patent system, so too are rules that elevate the consequences of harmless administrative error to the point of depriving a worthy inventor of the protections to which he is otherwise entitled.

Policy changes that are perceived to lessen the economic value of patents, or their certainty of enforcement, have an immediate impact on investment decisions, and a long-term impact on the quality of innovation itself. While some might be tempted to encourage infringement, or to lessen its financial consequences, in the name of short-term competition, any such savings are likely to be heavily outweighed by the cost to society of foregoing future innovation that would lower costs and improve quality of life.

Johnson & Johnson's interest in patent law reform is to insure that the patent system fairly rewards those who contribute to our society through the invention and development of new and useful products and processes. A fair, efficient and reliable patent system will continue to stimulate the investment in innovation that is necessary in today's technologically complex world to create the new products and processes that will lead to better lives for Americans and the rest of the world. In addition, the best promise for preserving and enhancing our place in an increasingly competitive global marketplace will be to stimulate U.S. investment in research-based industries.

Prompted in part by the recent studies by the FTC and NAS, attention has recently been focused on ways to improve our patent system. Last year, Congress appropriately provided increased funding to the U.S. Patent & Trademark Office in support of its 21st Century Strategic Plan to improve both patent quality and patent pendency. This was an excellent first step towards upgrading our patent system, and one that, if continued, should bear fruit in the years to come.

Although patent law reform has been discussed in Congress and elsewhere over time, PhRMA has only recently become more active in this debate. Unlike some other trade or bar associations, PhRMA did not develop proposals seeking patent law reform and submit them to the Subcommittee. Likewise, PhRMA has not developed a set of principles establishing what patent law reform means to PhRMA. That does not mean that PhRMA member companies are not interested. Representatives of a number of PhRMA member companies have contributed to the process (as have I), in their capacities as members of other organizations.

PhRMA only recently became directly engaged in the patent law reform discussions. PhRMA focused on provisions that the member companies believed to be detrimental to their patent rights and to our patent system. These provisions were perceived to be counter to the incentives for innovation that are fundamental to the patent system. Since then, PhRMA has taken part in good faith discussions with other patent system stakeholders.

Comments on the Substitute

The Subcommittee is now seeking input on the Substitute, which is the result of extensive work by the Subcommittee, including the development of many proposals that have been discussed at Congressional Hearings and elsewhere such as the NAS/AIPLA/FTC-sponsored Town Hall Meetings, and the refinement of much of the technical language is now contained in the Substitute.

As described further below, although the Substitute represents progress in moving towards a balanced and achievable patent reform bill that will improve the reliability of our patent system, many PhRMA member companies have expressed serious reservations about certain of its provisions

Many PhRMA member companies, and other patent owners, were pleased to see that the Substitute omits certain provisions seen as detrimental to the value of patents and to the patent system, including the provision of the original version of H.R. 2795 on injunctive relief (Section 7) and the provision that would permit post-grant oppositions to be started at any time in the life of the patent in response to a notice of infringement (the so-called "second window" of opposition of Section 9 of the bill). Those two provisions were principal drivers of PhRMA's opposition to H.R. 2795.

Many PhRMA members also see the Substitute's adoption of a first-inventor-to file patent system as a healthy step towards harmonizing our patent system with those around the world, while eliminating lengthy, costly and complex interference proceedings of a kind found in no other country.

As to the remainder of the Substitute's provisions, most PhRMA member companies oppose the proposed venue provision for several reasons. That provision is perceived to unduly restrict the venues in which an infringement action could be brought, thereby eliminating many venues where a patent owner should fairly be allowed to enforce its patents. This is particularly significant in situations where the patent owner wishes to sue several companies for infringement in the same jurisdiction, or where substantial evidence and/or witnesses are located in a venue disallowed by the venue provision of the Substitute. Second, the special treatment for plaintiff not-for-profit educational institutions is neither appropriate nor workable. Accordingly, many PhRMA member companies would oppose any bill that contains the Substitute's venue provision. A number of PhRMA member companies also identified issues with other provisions of the Substitute, most of which are addressed in the Coalition Text discussed below.

Comments on the Coalition Text

During the Congressional recess, many interested companies worked together to develop proposed language that would address their concerns and move closer toward a consensus document. Thus far, some 30 companies have announced their support for the "Coalition Text." PhRMA as an association has not taken a position on the Coalition Text, although several supporters of the Coalition Text are PhRMA members, with the remainder coming from a variety of other industries. The text modifies a number of provisions of the Substitute that were of concern to Coalition Text supporters and many other stakeholders.

The Coalition Text should be viewed as a "package." Unlike other packages, however, this package evolved through changes designed to garner the support of as many diverse companies as possible. Thus, as in any legislation involving compromise, there may be some changes that are included in the spirit of creating a consensus regarding at least some of the goals of patent law reform. In supporting the Coalition Text, many companies have accepted significant compromises in the expectation that this text would garner support from companies in other industrial sectors, such as IT and software companies that have most recently shown interest in provisions relating to transfer of venue and to "damages apportionment."

PhRMA member companies that support the Coalition Text, as Johnson & Johnson does, generally view this compromise as a balanced approach to patent reform.[1] This coalition package would provide significant advantages for owners of valid patents, while providing an opposition procedure that will provide a meaningful check on the quality of recently-issued patents. Subjective and intent-based invalidity issues would be largely removed from patent litigation, while ensuring that, like today, knowledge that is publicly accessible may still be used to assert that a patented invention is obvious.

Several provisions of the Coalition Text, as compared to the corresponding text in the Substitute, deserve special attention:

Venue

The Coalition Text includes a provision for transfer of venue in patent infringement actions that have been brought in jurisdictions without a substantial connection to the case, rather than limiting the available jurisdictions for bringing such a case to those where the defendant is found. This difference is important. Although there are significant policy reasons for limiting unfettered "forum shopping," there are also significant policy reasons not to restrict patent owners from bringing actions in jurisdictions, such as the parties' home jurisdictions or elsewhere, where significant evidence relating to the case may be located. The proposed transfer provision would have the benefit of preserving the patent owner's initial choice of venue if rationally

[1] A good summary of the overall provisions of the Coalition Text is contained in the covering page forwarded to the Subcommittee with the Coalition Text itself, which cover page is attached to this testimony. *See* Appendix.

connected to the parties or evidence, while permitting alleged infringers to transfer cases to more appropriate jurisdictions if the case has been brought in a jurisdiction without substantial connection to the matter to be decided. This provision will likely reduce forum shopping, and enhance the perceived fairness of our system of patent enforcement.

CREATE Act Preservation

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The Coalition Text would explicitly preserve the substance and intent of the recent CREATE Act. The Coalition Text contains modifications to the amendments to sections 102 and 103 contained in Section 3 of the Substitute. These provisions modify the re-codification of the CREATE Act provisions to eliminate certain unintended consequences of the language in the Substitute.

The Coalition Text also strengthens the inventor's one-year grace period under the law to protect academic publication of inventions from precluding later patenting of those inventions. Finally, the Coalition Text modifies the language concerning Section 115 in Section 4 of the Substitute to provide clarifications and reaffirm existing requirements governing declarations made in lieu of an oath.

Codification of *Georgia Pacific* Damages Factor 13 (Damages Apportionment)

The Coalition Text seeks to clarify several ambiguities in the provision of the Substitute on damages apportionment that became apparent during its development.

"Combination inventions" **-** In the Substitute, the limitation of the provision to combination inventions has been seen as problematic because, at some level, all inventions can be viewed as combinations. As Chief Judge Howard Markey of the Court of Appeals of the Federal Circuit once observed, "virtually all inventions are 'combinations,' and . . . every invention is formed of 'old' elements'…Only God works from nothing. Man must work with old elements." Howard T. Markey, "Why Not the Statute?," 65 P.Pat.Off.Soc'y 331, 333-34 (1983). Accordingly, the Coalition Text no longer refers to combination inventions. This will avoid needless litigation concerning whether any particular claimed invention is or is not a "combination."

"If relevant" **-** In the Substitute, the introductory phrase including the phrase "if relevant," was seen as perhaps creating a threshold relevancy standard that might complicate application of the provision. In the Coalition Text, this phrase is clarified to indicate that the provision is always relevant, although it should be weighed with (and may be outweighed by) other relevant factors.

"Realizable value" **-** In the Substitute, the use of the term "realizable value" was also seen as introducing ambiguity, as "value" may or may not be "realizable." In the context of *Georgia Pacific*, the terms "realizable profit" and "value" are used as alternatives, as they are in the Coalition Text.

"Inventive Contribution" - In the Substitute (and in early drafts of what later became the Coalition Text), the term "inventive contribution" was used to refer to the proportion of the "realizable value" that should be credited to the patented invention, as distinguished from that which should be credited to other factors, such as the infringer's contributions to the infringing product. As explained by BSA's witness, Mr. Lutton, in his written testimony, "BSA supports the Committee print's approach to provide courts with a statutory basis for . . . damages calculations *based on the proportional value of a patented invention alone, rather than on the cumulative value of all features included with a larger product."* (Subcommittee Hearing Transcript of April 20, 2005, Part I, at pg. 58, italics added). *See also* Prepared Statement of Honorable Bob Goodlatte, Hearing Transcript of April 20, 2005 at pg. 20, noting that the Committee Print "ensures that damages awarded to a party are proportional to the value that the party's invention contributes to the total value of the defendant's product." In the ensuing multi-lateral discussions that lead to the Substitute, the purpose of this damages provision was thus understood as being to codify *Georgia Pacific* damages factor #13, to thereby encourage its uniform application by the courts. *See Georgia-Pacific Corp. v. U.S. Plywood-Champion Papers Inc., 318 F.Supp. 1116, 1120 (S.D.N.Y. 1970).*

During the recent Congressional recess, however, it became clear that some were seeking to give the term "inventive contribution" quite a different and entirely unintended interpretation. In particular, it was suggested that in determining the credit to be given to the "inventive contribution," the patented invention should somehow be dissected into its various elements or sub-parts, and that the "realizable value" attributable to the "inventive contribution" contained in some, but not necessarily all, of these sub-parts should be used to determine the "realizable value" to be credited in the damages analysis.

Such an element-by-element or sub-part approach to determining realizable profit or value is plainly inconsistent with *Georgia Pacific,* and would be unprecedented in patent damages law. Because the patentee is required as a threshold to damages recovery to show that all of the elements of the patented invention are present in the infringing product or process, it would be illogical to deny the patentee credit for that showing when calculating damages. Adoption of an element-by-element or sub-part analytical approach would not only trivialize patent damages, but would lead to inconsistent and unfair damages awards.

Not surprisingly, once this alternate construction surfaced, any use of "inventive contribution" in this context quickly engendered substantial opposition, making its inclusion in any broad-based coalition draft entirely unacceptable.

The response of the American Bar Association Intellectual Property Law Section ("ABA-IPL") Council to such a construction of "inventive contribution" is representative. Earlier this year, the ABA-IPL passed Resolution TF-14A, which supported "codifying elements of the 'entire market value' rule," and which specifically endorsed the adoption of language referring to "the portion of the realizable profit that should be credited to the inventive contribution as distinguished from other features of the combination, the manufacturing process, business risks, or significant features or improvements added by

the infringer." At the same time, the ABA-IPL adopted Resolution TF-14B, opposing any legislation that would exclude value attributable to elements known in the prior art.

After learning of the different meaning being ascribed to "inventive contribution" in the Substitute, the ABA-IPL Section Council voted instead in favor of Resolution TF-14C:[2]

> RESOLVED, that the Section of Intellectual Property Law opposes, in principle, determination of which elements of a claim were the inventive contribution, in determining damages, and
>
> SPECIFICALLY, the Section opposes legislation providing that a determination of a reasonable royalty in the case of a combination invention shall consider, where relevant and among other factors, the portion of the realizable profit that should be credited to the inventive contribution as distinguished from other claimed features of the combination; and
>
> Past Resolution TF-14A is hereby rescinded.

To resolve the problem, the Coalition Text now includes damages apportionment language that clarifies that

> consideration shall be given to, among other relevant factors, the portion of the realizable profit or value that should be credited to the contributions arising from the claimed invention as distinguished from contributions arising from features, manufacturing processes or improvements added by the infringer and from the business risks the infringer undertook in commercialization.

Coalition Text, Section 6(a)(1)(B) at pg. 20. By using the defined term "claimed invention," this provision remains true to its original intent, and precludes the kind of misinterpretation suggested in connection with the use of the term "inventive contribution."

Based on these considerations, Johnson & Johnson, a number of other PhRMA member companies, and many companies from other industries, have urged the Subcommittee to adopt the Coalition Text.

PhRMA and Johnson & Johnson appreciate the invitation to provide our views to the Subcommittee and look forward to working with the Subcommittee on patent law reform and other matters.

[2] It is understood that the text of this Resolution has not yet been communicated to Congress by the ABA-IPL Section because it is currently undergoing the ABA's further required internal clearance procedures.